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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,038	10/31/2005	Johanna Roos	05822.0319USWO	6646

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EXAMINER	
HOBBS, LISA JOE	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
01/26/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,038	ROOS ET AL.	
	Examiner	Art Unit	
	Lisa J. Hobbs	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-56* is/are pending in the application.

4a) Of the above claim(s) *46-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/2005, 06/2009, 09/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 38-45 in the reply filed on 13 October 2009 is acknowledged. The traversal is on the ground(s) that the search would not be a burden since the method and kit are related. This is not found persuasive because there are considerations that pertain to each of the groups that do not pertain to the other group. Enablement, scope of enablement, written description, indefiniteness, etc., considerations differ between claims to methods of determining physiological elements and claims to products such as kits.

The requirement is still deemed proper and is therefore made FINAL.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement(s) (IDS) submitted on 11 January 2005, 25 June 2009, and 28 September 2009 is/are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

The drawings are objected to because there are panels which are not labeled and panels within the same figure which are labelled with the same designator. For example, Figure 5 has multiple panels designated panel A or panel B and some panels without designators. Also,

Figures 4 and 6 do not have any designators. As well, the Figures must match the specification and the Brief Description of the Drawings.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Sequence Rules Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2), for example, see pages 16 and 17 of the specification as well as Table 1. However, the application fails to comply with the requirements of 37 CFR 1.821 through 1.825. MPEP 2422.03 states that "37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given

sequence is also embedded in the text of the description or claims of an application. This requirement is also intended to permit references, in both the description and claims, to sequences set forth in the "Sequence Listing" by the use of assigned sequence identifiers without repeating the sequence in the text of the description or claims. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 243 of SEQ ID NO: 23" is permissible and the fragment need not be separately presented in the "Sequence Listing." Where a sequence is embedded in the text of an application, it must be presented in a manner that complies with the requirements of the sequence rules". The instant application contains sequence data but lacks a separate sequence listing section where all sequence data are provided individual designators. Failure to comply with the sequence requirement in response to this Office Action will result in the response being held non-compliant.

Claim Objections

Claims 39-45 are objected to because of the following informalities: in each claim there is a recitation of a named step from the parent, independent claim with further limitations added to that step. Although all of these claims are referring back to specific items in the independent claim for appropriate antecedent basis, none of the claims refers to "said" item, merely "the" item, as if the item were newly recited and did not have an antecedent. Claim 44 does recite "said" second antibody, but is the only claim which does this. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 38, with dependent claims 39-45, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what applicant intends to claim with the language "physiological conditions". This could refer to a large number of varying conditions such as temperature, pH, the presence of particular liquids, the type of sample, humidity, ionic strength, types of ions present, etc. It is unclear what "physiological conditions" applicant wishes to make limitations for the performance of this method. Also, included in the difficulty with the limitation "physiological conditions" is the fact that not every body fluid from a mammal will possess the same elements and it is unclear which body fluids other than blood, serum, and plasma will possess the physical elements such as complement pathway factors and particular ions, etc., to facilitate the performance of the method as described.

Claim 38, with dependent claims 39-45, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear in step a if the proteins and peptides recited in the limitation are in some way "against" C1q, etc., or if it is just the immunoglobulins intended for practice in the instant invention that are intended to be "against" the recited complex elements.

Claim 38, with dependent claims 39-45, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention. It is unclear in step b if the dilution has any limitations with regard to buffers, ionic strength, amounts, etc. For example, page 15 of the specification refers to particular buffers that could be used, but cautions that high ionic strength buffers could cause problems and should be taken into account.

Claim 38, with dependent claims 39-45, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear in step c if the ficolin binding carbohydrate is the element which activates the lectin pathway, in which case it is unclear what MBL does when added to the mix. If MBL also activates the lectin patway, then the claim should be rewritten to reflect that effect of MBL.

Claim 38, with dependent claims 39-45, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear in step d if the antibody is to the complete complex, as it appears it must be from the specification at page 17. The claim limitation appears to leave open the possibility that the antibody could recognize anything in the complex. It is also unclear what applicant intends to claim with the limitation "autologous" C5b-9 complex.

Claim 42, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention. It is unclear that every carbohydrate encompassed by the limitation "synthetic carbohydrate" or "microbial polysaccharide" would be functional in the instant method. Page 16 of the specification mentions that the lectin pathway can be triggered by "synthetic carbohydrate conjugates", but that is not what is recited in the claim.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa J. Hobbs whose telephone number is 571-272-3373. The examiner can normally be reached on Hotelling - Generally, 9-6 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lisa J. Hobbs/

Primary Examiner
Art Unit 1657

ljh